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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,790	01/14/2002	Richard A. Rosenbloom	QUIG-1006CIP	3053

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EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding..

Office Action Summary	Application N .	Applicant(s)	
	10/045,790	ROSENBLOOM, RICHARD A.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *21-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This application is a continuation in part of 09/993,003.

Information Disclosure Statement (IDS)

Applicants' IDS submitted March 26, 2002 in Paper No. 2 is acknowledged. Some non-patent literature documents, e.g., downloading from internet, have been crossed out as they are not appropriate for IDS, i.e., no name of author and no publication data (e.g., date and page) provided.

Election/Restrictions

Applicant's election with traverse of the invention of Group I, Claims 1-20 and the species election of vitamin D3 as the compound in 17 and ascorbyl palmitate as the antioxidant in Paper No. 6, submitted July 30, 2002 is acknowledged.

The traversal is on the ground(s) that inventions I and II are not separate patentable since the method herein in Group I requires the composition in Group II. This is not found persuasive. As discussed in the "Restriction Requirement" in the previous Office Action mailed April 23, 2002 (see page 2), the composition containing interleukin-1-α derivatives can be practiced in a method for the prevention, reduction, or treatment of radiation injury in a method of conditions associated with cephalic pain and alleviating the symptoms associated therewith. Therefore, the criteria for distinct inventions: (1) the process for using the product as claimed can be practiced with another materially

different product since the composition containing interleukin-1-α derivatives is another materially different product -- which is materially different from the product as claimed.

The requirement is therefore made FINAL.

Therefore, claims 21-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The claims have been examined insofar as they read on the elected specie.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In the instant case, the inclusion of "one or more compounds effective to regulate at least one of cell differentiation and cell proliferation" in claim 1-20, "one or more antioxidants" in claim 1, "structurally similar derivatives thereof which exhibit antioxidant activity" in claim 4, and "one or more antioxidant enzymes" in claim 6, and "anti-inflammatories" in claim 12, is not enabled by the specification. Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al.* 37 USPQ 466

(US1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exist not only when a claim is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFA, 1997) at 1406: stating this usage does "little more than outline goal appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". Applicants functional language at the points of novelty fails to meet the requirements set forth under 35 U.S.C. 112, first paragraph. Claims employing functional language at the exact point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limited of monopoly asserted" (*General Electric Company v. Wabash Appliance Corporation et al. supra*, at 468).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable

one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to a method for the **prevention of** radiation injury. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Nature of the invention: The instant invention pertains to the compositions for preventing radiation injury.

The state of the prior art: The skilled artisan would view that preventing radiation injury is highly unlikely since prevention (i.e., total prevention) of radiation injury is considered lack of medical basis to one of ordinary skill in the art.

The predictability or lack thereof in the art: The skilled artisan would view that preventing radiation injury is highly unpredictable.

The presence or absence of working examples: In the instant case, **no** working examples are presented in the specification as filed showing how to prevent radiation injury herein.

Therefore, in view of the *Wands* factors, as discussed above, e.g., the amount of direction or guidance provided, absence of working examples, and the predictability of the art, Applicants fail to provide information sufficient to practice the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The "one or more compounds effective to regulate at least one of cell differentiation and cell proliferation" in claim 1-20, "one or more antioxidants" in claim 1, "structurally similar derivatives thereof which exhibit antioxidant activity" in claim 4, and "one or more antioxidant enzymes" in claim 6, and "anti-inflammatories" in claim 12 render claims 1-20 indefinite as failing to clearly set forth the metes and bounds of the patent protection desired. Therefore, the scope of claims is indefinite as to the composition encompassed thereby.

The expression "selenium compounds" in claim 10 renders claim 10 indefinite. The expression "selenium compounds" is not defined in the specification and claim. Therefore, the scope of claims is indefinite as to the composition in the claimed method herein encompassed thereby.

The expression "non-U.S.P. hydrophilic" in claim 17 renders claim 17 indefinite. The term "non-U.S.P. hydrophilic" is not defined in the specification and claim. Therefore, the scope of claims is indefinite as to the composition in the claimed method herein encompassed thereby.

The expression "substantially" in claim 17 is a relative term which renders claim 17 indefinite. The term "substantially" is not defined in the specification and claim. Therefore, the scope of claims is indefinite as to the composition in the claimed method herein encompassed thereby.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over KITA, K (WO 9718817, PTO-892, equivalent to 6,162,801), and Bissett et al. (GG, PTO-

1449) and Darr et al. (GH, PTO-1449) in view of Shimoi et al. (AK, PTO-1449) and Kim et al. (5,776,460, PTO-892)

Kita discloses that vitamin D including vitamin D3 (cholecalciferol), is useful in a dermatological composition for the protection and treatment of the skin and scalp from harmful UV radiation. See 6,162,801, abstract, col.1 lines 22-24 and 51-67, col.4 lines 13-16, and col.8 lines 51 to col. 9.

Bissett et al. discloses that an antioxidant alone such as vitamin C (asorbic acid), or in combination with an anti-inflammatory agent are useful in treating UV radiation-induced chronic skin damage in a mammal. See abstract, page 86 1st paragraph, and Discussion in page 90.

Darr et al. discloses that vitamin C such as asorbic acid or vitamin E is useful in a composition to be administered orally or topically in the treatment of the protection of UV radiation-induced damage. See Summary and page 247.

The prior art does not expressly disclose the employment of the combination of vitamin D3 and ascorbyl palmitate in a composition to be administered in a method for the treatment or reduction of radiation injury. The prior art does also not expressly disclose the composition herein further comprising flavonoid / flavonoid derivatives, and ginseng.

Shimoi et al. discloses that flavonoid / flavonoid derivatives from plant or tea are antioxidants and have radioprotective effects. See abstract.

Kim et al. discloses that ginseng is known to be useful in the protection of radiation injury. See col.1 lines 21-27.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the combination of vitamin D3 and ascorbyl palmitate in a composition to be administered in a method for the treatment or reduction of radiation injury, and to further comprise flavonoid / flavonoid derivatives, and ginseng in the claimed method.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the combination of vitamin D3 and ascorbyl palmitate in a composition to be administered in a method for the treatment or reduction of radiation injury since vitamin D such as vitamin D3 is known to be useful for the protection and treatment of the skin and scalp from harmful UV radiation. Antioxidants such as vitamin C (asorbic acid) is known to be useful in the treatment and the protection of UV radiation-induced damage. Moreover, ascorbyl palmitate is a known vitamin C (an ester of asorbic acid). Therefore, one of ordinary skill in the art would have reasonably expected that combining vitamin D3 and ascorbyl palmitate known useful for the same purpose, i.e., treating radiation damage, in a composition to be would improve the therapeutic effect in treating radiation injury.

Further, both flavonoid / flavonoid derivatives and ginseng are known antioxidants and also known to be useful in the protection of radiation injury. Therefore, one of ordinary skill in the art would have reasonably expected that further adding both flavonoid / flavonoid derivatives and ginseng to the composition herein known useful for the same purpose, in a composition to be administered would provide additive effects for the therapeutic treatment in radiation injury.

Since all active composition components herein are known to useful to treat radiation injury, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. A. Jiang, Ph.D.
Patent Examiner, AU 1617
October 7, 2002

SREENI PADMANABHAN
PRIMARY EXAMINER
10/11/02